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IN THE

Supreme Court of the United States

KSR INTERNATIONAL CO.,

Petitioner,

—v.—

TELEFLEX INC., and TECHNOLOGY HOLDING CO.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association (AIPLA) is a voluntary bar association of over 16,000 members who work daily with patents, trademarks, copyrights, trade secrets, and the legal issues that such intellectual property presents.[1] Members include attorneys in private and corporate practice as well as government service, whose work routinely involves intellectual property rights. In the litigation context, AIPLA's members are equally split between plaintiffs and defendants. As part of its central mission, AIPLA is dedicated to encouraging the healthy development of patent law. Accordingly, AIPLA has a vital interest in the issue presented by this case, which will have a far-reaching impact on patent rights.

The question before this Court is whether there must be a reason (*i.e.*, a teaching, suggestion or motivation recognizable by one of ordinary skill in the relevant art) to combine separate prior art teachings before an invention can be deemed unpatentable. This requirement is a necessary part of the nonobviousness standard codified at 35 U.S.C. § 103(a). It prevents use of an invention itself as the template to find individual pieces in the prior art and then declare the invention obvious based on hindsight. (As discussed below, contrary to what this Court has been told,

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[1] Consents to file this brief from the counsel of record for all parties are on file with the Clerk of the Court pursuant to Supreme Court Rule 37.3(a). This brief was not authored, in whole or in part, by counsel to a party, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA or its counsel. After reasonable investigation, AIPLA believes that no member of its Board or Amicus Committee who voted to prepare this brief on its behalf, or any attorney in the law firm or corporation of such a board or committee member, represents a party with respect to this litigation. Some committee members or attorneys in their respective law firms or corporations may represent entities which have an interest in other matters which may be affected by the outcome of this litigation.

the Federal Circuit has not created a blanket requirement that the reason must be explicitly written in the prior art.) This issue and the statute underlying it are at the heart of the Constitutionally-authorized patent system.[2] With good reason it has been called "probably the most important section in the whole Patent Code."[3]

AIPLA believes that the current, well-defined and evolved analytic framework which looks for a reason – referred to as a teaching, suggestion or motivation ("TSM") – before allowing a combination of prior art to render an invention unpatentable draws upon and articulates the principles found in the decisions of this Court, as discussed *infra*. Those decisions required an identifiable reason to combine separate elements in the prior art. This reason may be found in the prior art itself, or in the general knowledge of one of skill in the art, or by the nature of the problem to be solved. TSM excludes using the patent itself as the reason to combine prior art (an easy temptation for a court or jury). AIPLA believes TSM accords with the statutory requirements and its continued implementation is of vital import to the patent system. Accordingly, although AIPLA has no interest in the ultimate victor in this case, it submits this brief in favor of Respondents to urge this Court to continue requiring a reason before combining prior art to establish obviousness under section 103(a).

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[2] U.S. CONST. art. 1, § 8, cl. 8 ("The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."). This "clause is both a grant of power and a limitation." *Graham v. John Deere Co*, 383 U.S. 1, 5-6 (1966); *see Eldred v. Ashcroft*, 537 U.S. 186, 212 (2003)(*citing Graham*).

[3] George E. Frost, "Future Considerations – Views of a Corporate Counsel" (1978) *in* NON-OBVIOUSNESS –THE ULTIMATE CONDITION OF PATENTABILITY at 8:101 (J.F. Witherspoon ed., Bureau of National Affairs, 1980) (hereinafter "ULTIMATE CONDITION").

SUMMARY OF ARGUMENT

Title 35, United States Code says anything "new" presumptively is entitled to patent protection if it complies with the other provisions of the patent statutes. *See* 35 U.S.C. § 101. Human nature, however, is to rely on hindsight – declaring any combination obvious using present knowledge and therefore unpatentable.

"Hindsight is an exact science"[4] where the outcome already is known", which as Billy Wilder famously put it "is always twenty-twenty."[5] The difficulties caused by hindsight are not new; they have been recognized from time immemorium. King Solomon wrote in the Bible, at the beginning of *Ecclesiastes*, 1:9-10, that everything new can actually be traced to what came before it:

> *What has been is what will be,*
> *and what has been done is what will be done;*
> *there is nothing new under the sun.*
>
> *Is there a thing of which it is said,*
> *"See, this is new";*
> *It has already been, in the ages before us.*

And no doubt it was this same belief that all things are merely created by combining old parts which led Sextus Julius Frontinus, an engineer and Roman Governor of Britain, to write in the First Century that all weapons of war and siege already had been invented.[6] Clearly this was and

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[4] Guy Bellamy, The Sinner's Congregation (Secker & Warburg, 1982), *quoted at* http://www.bartleby.com/63/47/4874.html.

[5] John R. Columbo, Columbo's Hollywood: Wit And Wisdom Of The Movie Makers (Collins 1979), *quoted at* http://www.bartleby.com/66/99/64699.html.

[6] *Strategemata*, Intro. to Book 3 (ca 84 A.D.) (Loeb ed. transl. 1925), *available at* http://penelope.uchicago.edu/Thayer/E/Roman/Texts/Frontinus/Strategemata/3*.html ("Laying aside also all considerations of works and engines of war, the invention of which has long since reached its

(footnote continued ...)

is not the case, as the last 2,000 years have demonstrated. It is no less true with patentable inventions.[7]

Patentability does not (and should not) turn on whether the invention can be broken into individual elements found in the prior art, as this will virtually always be the case; it turns on whether one of ordinary skill in the art would have thought it obvious at the time to combine the individual elements in the manner claimed. *See In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998)("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue."). As Chief Judge Howard Markey, the first Chief Judge of the Federal Circuit, explained, "virtually all inventions are 'combinations', and ... every invention is formed of 'old elements' ... Only God works from nothing. Man must work with old elements." H.T. Markey, "Why Not the Statute?", 65 J. Pat. Off. Soc'y 331, 333-34 (1983). It is for this reason that Section 103 requires considering whether one of ordinary skill in the art world have found the invention as a whole obvious, *i.e.*, would that person have had a reason to make the claimed combination?

The conversational, informal analysis that Petitioner and supporting *amici* utilize would only require identification of individual elements in the prior art to show an invention obvious. What they propose is hindsight and gives no insight into whether "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C.

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limit, and for the improvement of which I see no further hope in the applied arts...").

[7] There is an apocryphal story, long-doubted as myth, that a Patent Office official in the 1800's advocated closing the Patent Office because everything that could be invented already had been invented. Quote attributed to Charles H. Duell, U. S. Commissioner of Patents *see* http://www.ideafinder.com/guest/archives/wow-duell.htm.

§ 103(a)(emphasis added). The reason the statute relies upon the hypothetical Person Having Ordinary Skill In The Art (some use the acronym "PHOSITA") is to prevent this misapplication of otherwise random elements by combining them based upon nothing more than the inventor's own work. The proposals do nothing more than confirm the existence of the elements without indicating if one of ordinary skill in the art would have combined them. In essence, "the claims [are] used as a frame, and individual, naked parts of separate prior art references [] employed as mosaic to recreate a facsimile of the claimed invention," *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552 (Fed. Cir. 1983), without a reason to do so.

Petitioner and some *amici* supporting reversal misstate the Federal Circuit's TSM analysis, asserting that the Federal Circuit always has required written proof explicitly suggesting the claimed combination.[8] As the analysis evolved, panel decisions occasionally have required a writing – some have argued this was done erroneously, while others argue that these cases are limited to their facts – but it is clear that the Federal Circuit has rejected an explicit, blanket writing requirement: "[T]he motivation to combine need not be found in prior art references, but equally can be found 'in the knowledge generally available to one of ordinary skill in the art.' Evidence of a motivation to combine references need not be in the form of prior art." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322 (Fed. Cir. 2005); *see also, National Steel v. Car, Ltd. v. Canadian Pac. R.R., Ltd.*, 357 F.3d 1319, 1337-1338 (Fed. Cir. 2004)("The motivation to combine can be located either

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[8] *E.g.*, Petitioner's Brief at 19; Brief of the Business Software Alliance at 2 ("elevates objective documentation") and 14 ("directing the courts to look only at published materials..."); Brief of AARP et al. at 8 ("Federal Circuit's 'suggestion' test ... looks almost entirely to the contents of the prior art references to demonstrate obviousness").

in a prior art reference, or it can be implicit in the knowledge of one of ordinary skill in the art." (citations omitted)). The approach now employed by the Federal Circuit follows the statute and this Court's decisions.

TSM is a well-established, thoughtfully-analytic framework that provides certainty and uniformity in obviousness determinations while allowing proper flexibility. By requiring a showing of why someone of ordinary skill in the relevant art would think the invention obvious, it functions as a critical evidentiary device that prevents arbitrary decisions driven by hindsight.

Petitioner and its supporting *amici* (notably the Government) seek to eliminate any analytic framework whatsoever or suggest tests to replace the TSM analysis. These tests, however, ignore the substantial risks of hindsight, ignore the statutory language, ignore the roots of TSM analyses, and do not comport with this Court's decisions requiring a reason someone of skill in the art would combine prior art before holding that there are only obvious differences between the patented invention and the prior art as a whole. Further, they improperly shift the evidentiary burden to the patentee by ignoring the statutory presumption that an issued patent is valid (35 U.S.C. § 282). They instead seek to set aside a well-established legal framework that is consistent with precedent and statute for fact-driven, technology-related individualistic reasons. While asserting that the Federal Circuit has departed from *Graham*, they raise the same issues and arguments as the *Graham* Court rejected when those petitioners and *amici* also raised them.[9] As discussed *infra*, these proposals should be

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[9] *Graham*, 383 U.S. at 19 ("We have been urged to find in § 103 a relaxed standard, supposedly a congressional reaction to the 'increased standard' applied by this Court in its decisions over the last 20 or 30 years. The standard has remained invariable in this Court. Technology, however, has advanced – and with remarkable rapidity in the last 50 years.").

rejected. They are inappropriate and unworkable, particularly in the context of a summary judgment appeal, as here.

In the present case, the Federal Circuit reviewed a grant of summary judgment, where factual disputes must be resolved against the movant. *E.g., Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The trial court did not make specific findings concerning a key claim element requiring attachment, but instead merely addressed combining elements generally. (*Compare* Appendix 12a and 15a-16a *with* 26a-27a, 34a and 45a). In part because the trial court failed to make a complete obviousness determination to support summary judgment, the Federal Circuit remanded for further proceedings. Appendix 16a-17a. The opinion does not address the ultimate question of obviousness, but remands for failure to meet the standard of proof required on summary judgment. Petitioner still can show obviousness below, if appropriate, and so the remand should be affirmed.

ARGUMENT

In analyzing whether an invention is patently new,[10] Judge Learned Hand eloquently articulated the issue of obviousness:

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[10] 35 U.S.C. § 101 provides that a person "may obtain a patent" on "any new and useful process, machine, manufacture, or composition of matter." Section 102 provides that "[a] person shall be entitled to a patent unless - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent..." Both presume entitlement to a patent. Section 103 functions only to limit this entitlement by explaining that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102" if it would be obvious to one of skill in the art at the time the invention was made – it does not operate to eviscerate the preceding sections by placing the burden on the patentee to prove entitlement to a patent.

> In appraising an inventor's contribution to the art, ... the most reliable test is to look at the situation before and after it appears. Substantially all inventions are for the combination of old elements; what counts is the selection, out of all their possible permutations, of that new combination which will be serviceable. No objective standard is practicable ...

Safety Car Heating & Lighting Co. v. General Elec. Co., 155 F.2d 937, 939 (2d Cir. 1946)(emphasis added). Determining the reason for "the selection" is what Judge Hand identified as the essence of section 103(a)'s obviousness analysis. *Graham* also recognized that it would take a case-by-case analysis to articulate the parameters for providing a reason to combine. 383 U.S. at 18 ("What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter and should be amenable to a case-by-case development."). Section 103(a) sets the standard for considering whether to combine prior art. The Federal Circuit has done this in developing the TSM analysis since *Graham*.

1. SUPREME COURT PRECEDENT REQUIRES A REASON TO COMBINE PRIOR ART

Petitioner asserts that requiring a reason to combine prior art is a departure from this Court's precedent, alleging that in more than 150 years of decisions none has held that "a proven 'teaching, suggestion or motivation to combine prior art teachings in the particular manner claimed in a patent'" is necessary for obviousness. Petitioner's Brief at 19. In fact, a careful review shows that this requirement, and the Federal Circuit's implementation of it under the TSM framework, is necessary and consistent with this Court's jurisprudence. It is a flexible standard, but one that requires

identifying a reason why a person of ordinary skill at that time would have combined prior art. Absent this identification, a reviewing court must "infer that the Board [or trial court] used hindsight." *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). As set forth below, the TSM analysis is in keeping with this Court's precedent and should be upheld.

A. THE TEACHING-SUGGESTION-MOTIVATION ("TSM") ANALYSIS ADHERES TO LONG-STANDING PRINCIPLES OF THIS COURT

Obviousness is an after-the-fact determination. It asks whether at the time of the invention one of ordinary skill in the art would have thought that the invention as a whole was obvious over what came before it. The question can be easily answered where the prior art explicitly sets forth the combination, providing an anticipation (lack of novelty under section 102), which has been called the "epitome of obviousness." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).[11] If the entire invention is not disclosed literally or inherently in a single piece of prior art, however, then section 103(a) applies and the hypothetical analysis of whether one of ordinary skill would have combined separate prior art teachings must be undertaken.

Petitioner asserts that the need for a "suggestion" or "reason" to combine cannot be found in this Court's precedent. In fact, the Court has required a "suggestion" or "reason" in some of its earliest decisions, including:

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[11] Where a single prior art reference discloses an invention literally or inherently, it is anticipated under 35 U.S.C. § 102 (novelty). This is a separate test of patentability. *United States v. Adams*, 383 U.S. 39, 48 (1966). Section 103 is only reached if "the invention is not identically disclosed or described as set forth in section 102." 35 U.S.C. § 103(a). Unlike the obviousness analysis, for anticipation, there is no reason to inquire into what one of ordinary skill would have hypothetically thought at the time.

- In 1889 this Court held an invention obvious because it "would naturally suggest itself to any mechanic, and that its use in that way is within the range of common knowledge and experience." *Day v. Fair Haven & Westville Ry. Co.*, 132 U.S. 98, 102 (1889)(emphasis added).

- In 1900 the Court looked to whether the claimed invention was "anything more than would have been suggested to an intelligent mechanic" *Mast, Foos, & Co. v. Stover Mfg. Co.*, 177 U.S. 485, 494 (1900) (emphasis added).

- The Court explained in 1909 that "he who first makes the discovery has done more than make the obvious improvement which would suggest itself to a mechanic skilled in the art," and found an invention patentable because "[t]here is nothing in the prior art that suggests the combined operation of the Golding patent in suit." *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 381 (1909)(emphasis added).

- In 1934 this Court held that the addition of an element to an old device was patentable only when "it was the result of invention, not the mere exercise of skill in the calling and not one plainly indicated by the prior art." *Electric Cable Joint Co. v. Brooklyn Edison Co.*, 292 U.S. 69, 79 (1934)(emphasis added).

Section 103(a) did not overrule these holdings. *Graham* explicitly stated that the statute codified this Court's precedent and did not change the standard previously applied.[12]

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[12] The 1952 Act codified decisions such as *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850), while "plac[ing] emphasis on an inquiry into obviousness." *Graham*, 383 U.S. at 3-4 and 16-17; *see also Dann v. Johnston*, 425 U.S. 219, 225-26 (1976) (same). It did not create a "relaxed standard" for obviousness. "The standard has remained invariable in this Court," and Congress did not change "the general level of patentable invention." *Graham*, 383 U.S. at 17-19.

Moreover, the decision in *Adams*, 383 U.S. 39, a companion case to *Graham*, confirms that there must be a suggestion to combine individual components to arrive at the claimed invention for obviousness.

The patent in *Adams* involved a battery with components well-known in the art. The issue was whether one of ordinary skill in the art would have had reason to combine these components, as claimed, in light of the prior art.

> It begs the question, and overlooks the holding [below], to state merely that magnesium and cuprous chloride were individually known battery components ... the issue is whether bringing them together as taught by Adams was obvious in light of the prior art.

Id. at 50 (emphasis added). *Adams* found that the mere identification of individual elements in the prior art was insufficient to answer the obviousness inquiry. Since there was no reason to bring the individual components together, the Court explained, there was no basis to find the invention would have been obvious to one of ordinary skill in the art:

> Despite the fact that each of the elements ... was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore [how the elements were separately used in that art, which] ... when taken together, would we believe, deter any investigation into such combination as is used by Adams.

Id. at 51-52. The origins for requiring a reason why one of ordinary skill would have combined individual elements found in potentially disparate references to arrive at the claimed invention are found both in the statute itself (which considers "the subject matter as a whole") and in this Court's precedent.

The decision in *Graham* also utilized what has been come to be known as *secondary considerations*, or "legal inferences or subtests," to implement the obviousness standards taking into account real world factors. *Graham*, 383 U.S. at 17-18, 36. These include whether the invention was commercially successful, if those in the art had long sought such an invention to solve a recognized need, and if the art taught away from combining prior art to create the claimed invention. They are useful to determine nonobviousness but differ from the TSM analysis, which considers whether there is a reason to combine.

Petitioner and some *amici* characterize the Federal Circuit's TSM analysis as a completely "new" requirement, created by the Federal Circuit in an open rejection of this Court's precedent. *E.g*, Petitioner's Brief at 19. This is incorrect, as shown by decisions of the Federal Circuit and its predecessor, the Court of Custom and Patent Appeals ("CCPA"). Even before *Graham*, in keeping with this Court's decisions the CCPA required a reason to combine prior art disclosures. *E.g., In re Bergel*, 292 F.2d 955, 956-57 (CCPA 1961)("The mere fact that it is possible to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.") (emphasis added). After *Graham*, the CCPA inquiry continued to seek a reason why isolated prior art teachings corresponding to each component would have been combined before holding an invention obvious. *In re Passal*, 426 F.2d 828, 831 (CCPA 1970).[13] The CCPA required a

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[13] The CCPA's decisions are binding precedent on the Federal Circuit. *See South Corp. v. United States*, 690 F.2d 1368 (1982)(*en banc*). The CCPA's patent-related docket focused on appeals from the Patent Office. Accordingly, after *Graham* the CCPA began to articulate a standard that would enable Patent Examiners to determine just what evidence beyond the mere identification of individual elements in the prior art

(footnote continued ...)

reason, a suggestion, to combine prior art disclosures to render the invention as a whole obvious. *In re Adams*, 356 F.2d 998, 1001-1002 (CCPA 1966).

At different times, the CCPA and then the Federal Circuit have emphasized one of the synonyms ("suggest" or "teach" or "motivate") more than another, but the use of these essentially interchangeable terms clearly invokes the same analysis for determining whether there was a reason to combine. Under any name, however, the CCPA, and later the Federal Circuit, has consistently applied the principles embodied in section 103(a) and this Court's precedent.

B. EXPLICIT WRITTEN MOTIVATION IS NOT REQUIRED

Petitioner and supporting *amici* maintain that the TSM analysis imposes a virtually insurmountable burden, requiring an explicit, written motivation specifically proposing the precise combination of prior art that leads to the claimed invention. *See* note 8, *supra*. It has no such requirement. The Federal Circuit explicitly has recognized that a written motivation is rare. *In re Johnston*, 435 F.3d 1381, 1385 (Fed. Cir. 2006) ("An explicit teaching that identifies and selects elements from different sources and states that they should be combined in the same way as the invention at issue, is rarely found in the prior art.") The TSM approach "does not provide a rule of law that an express, written motivation to combine must appear in prior art references before a finding of obviousness." *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004). The Federal Circuit has rejected such a rule:

> [Applicant] urges this court to establish ... [that] references may not be combined ... absent an

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distinguishes a nonobvious invention from an obvious one. *See, e.g., Bergel*, 292 F.2d at 956-57; *In re Adams*, 356 F.2d at 1001-1002.

> express suggestion in one prior art reference to look to another specific reference. We reject that recommendation as contrary to our precedent which holds that for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references.

In re Nilssen, 851 F.2d 1401, 1403 (Fed. Cir. 1988), *citing In re Sernaker*, 702 F.2d 989, 995 (Fed. Cir. 1983), and *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). It simply requires evidence that there is a reason one of ordinary skill would have contemplated the combination before reading the patent's disclosure, to ensure that the analysis is not based on hindsight.[14]

As the TSM analysis evolved, Federal Circuit panels sometimes have applied a more rigorous standard, at times even requiring a writing. This stringency has not been commonly applied and appears to be fact-specific to the case. Some have sought to characterize this as an absolute rule,[15] but AIPLA believes that these decisions should not be read to require a strict writing requirement. *See, e.g., Dystar Textilfarben GmbH, v. C.H. Patrick Co.*, No. 06-1088, -- F.3d --, slip op. at 15-26 (Fed. Cir. Oct. 3, 2006).

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[14] The "suggestion or motivation to combine references does not have to be stated expressly." *Medical Instrumentation & Diagnostics Corp. v. Elektra AB*, 344 F.3d 1205, 1221(Fed. Cir. 2003)(emphasis added). *Accord Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997); *B.F. Goodrich, Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996); *Cross Med.*, 424 F.3d at 1322.

[15] For instance, *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999), where the Federal Circuit reversed an obviousness holding for decorated Halloween leaf bags because the Board had not provided a specific analysis showing where the art taught a "reference-by-reference, limitation-by-limitation" reason to combine, the issue was first broached by the Government on appeal.

The TSM analysis looks for a reason to combine prior art; that reason can be found explicitly or implicitly in the prior art, it can flow from the nature of the problem solved by the invention, or it can come from the knowledge of those skilled in the art at the time of the invention. *In re Kahn*, 441 F.3d at 988; *see also, SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000). So long as there is a reason to combine there are no hard and fast rules. (There are numerous cases where patent claims have been found invalid or unpatentable for obviousness without any explicit written motivation, as set out in the footnote.[16]) In keeping with *Graham*, 383 U.S. at 17, the TSM methodology is flexible. *In re Johnston*, 435 F.3d at 1385 ("Many factors are relevant to the motivation-to-combine ... such as the field of the specific invention, the subject matter of the references, the extent to which they are in the same or related fields of technology, the nature of the advance made by the applicant, and the maturity and congestion of the field.")

Petitioner asserts that the TSM analysis can be satisfied only by an explicit writing is wrong. Applying TSM requires a non-hindsight reason, nothing more.

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[16] *E.g., Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996); *In re Huang*, 100 F.3d 135, 139 n.5 (Fed. Cir. 1996); *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 78 F.3d 540 (Fed. Cir. 1996); *In re Gartside*, 203 F.3d 1305, 1320-21 (Fed. Cir. 2000); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362 (Fed. Cir. 2003); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270; *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.* 411 F.3d 1332, 1338-9 (Fed. Cir. 2005); *In re Kahn*, 441 F.3d at 988-990. Indeed, the Federal Circuit recently reiterated that the reason for combining prior art references need not be explicitly stated in the art. *See Ormoco Corp. v. Align Tech., Inc*, No. 05-1426, -- F.3d --, slip. op. at 12-13 (Fed. Cir. Aug. 30, 2006), and *Alza Corp. v. Mylan Labs., Inc.*, No. 06-1019, -- F.3d --, slip op. at 4-7 (Fed. Cir. Sept. 6, 2006).

C. THE TSM ANALYSIS APPLIES ESTABLISHED LAW

This Court's prior decisions undermine Petitioner's complaint that the Federal Circuit's TSM analysis is divorced from precedent. Those opinions spoke of a "suggestion" in bringing elements together in light of the prior art. The Federal Circuit and its predecessor court merely brought that concept forward as the TSM analysis, not as a "new" requirement for obviousness never before applied. It provides certainty by defining the principles that have historically been applied by this and other courts, and it is in keeping with *Graham*.

TSM embodies the long-held requirement that it is not enough to simply find the individual elements of an invention in diverse prior art teachings. Rather, the analysis must focus on the invention as a whole. There must be evidence that one of skill in that art understood "at the time invention was made" that they could be combined while forgetting the claimed invention. The standard is flexible, but it exists as a rubric to prevent hindsight analysis and is important to maintain.

2. THE TSM ANALYSIS IS VITAL TO THE PATENT SYSTEM

The TSM analytic framework fulfills at least three critical functions: (1) it protects against hindsight, (2) it provides the needed flexibility to address questions of obviousness where fact patterns differ, and (3) it provides certainty and predictability in the methodology of obviousness determinations due to the long history of its use. It is a critical component in separating new combination inventions from unpatentable ones. It should not be disturbed.

A. THE ESTABLISHED STANDARD PREVENTS HINDSIGHT AND ARBITRARY DECISIONS

In Paradise Lost, the 17th century English poet John Milton described fallen angels as immediately declaring gunpowder obvious once it was shown to them:

> *The invention all admired, and each how he*
> *To be the inventor missed; so easy it seemed,*
> *Once found, which yet unfound most would have thought,*
> *Impossible!*

John Milton, PARADISE LOST, Part VI, l. 478-501, quoted in *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 726 (1990). The same occurs in real life too, where inventions are called "obvious" once revealed.

Section 103(a) therefore imposes a difficult hypothetical burden, determining whether the invention as a whole would have been obvious to one of ordinary skill in the art when "the invention was made." Thus, the legal framework must employ a standard that analyzes the art just prior to creation of the invention without knowing the invention, in order to distinguish "obvious" inventions combining old elements from "non-obvious" ones that also combine old elements.

Graham explicitly cautions that standards are needed "to 'guard against slipping into use of hindsight,' and to resist the temptation to read into the prior art the teachings of the invention in issue." 383 U.S. at 36 (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)). TSM is this guard.

The TSM framework recognizes that whether an invention would be obvious to one of ordinary skill lies not just in whether (s)he would be capable of combining the individual elements, but whether that hypothetical person would have selected the individual elements from the prior

art and then put them together "as a whole" in the manner claimed:

> The inventor has available ... thousands of ideas, elements, thoughts, screws, racks, pinions, feedback circuits, materials, pumps, discriminators, and the Super Bowl score. Ninety-nine percent of his information is chaff information, not only totally unuseful for his purpose, but misleading him down blind alleys. Often, he does not know where the wheat information is, or whether it exists ... But merely removing the chaff art and putting the prior art elements in physical juxtaposition near each other, made the invention obvious at once to us all.

Tom Arnold & Floyd R. Nation, "Proving Section 103 Nonobviousness" (1978), *in* ULTIMATE CONDITION, at 4:17-18. Had the inventor not done the selection of relevant elements (most of which likely appear in the prior art), separating the wheat from the chaff, there would not have been any invention – but having done so there may well be a patentable advance.

An infringer, on the other hand, has the patent as a guide and uses it to embark on a search for prior art showing each element "to prove patent invalidity, after the patented combination is proved to work, they have faith where the inventor could only speculate, whether this combination will work better than 100 others that come to his mind." Arnold & Nation, at 4:41. *See Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983) ("It is wrong to use the patent in suit as a guide through the maze of prior art references ... Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law."). Section 103(a) restrains this type of unbridled hindsight advantage:

> A test which looks solely to the operation of elements after they are combined must necessarily be premised on the unsound assumption that it is always obvious to take known things and combine them. It is the very unification of the elements, where the prior art fails to suggest such an action, that represents the advancement; and the test of patentability should be directed to this factor.

Herbert H. Mintz & C. Larry O'Rourke, "The Patentability Standard in Historical Perspective: 'Invention' to Section 103 Nonobviousness" (1977), *in* ULTIMATE CONDITION, at 2:216 (footnote omitted)(emphasis in original).

This Court has recognized the inquiry will not be easy. *Graham*, 383 U.S. at 36. Unlike other areas of law, where concepts largely can be understood by reference to experiences, obviousness demands that the court and jury step into areas of technology foreign to everyone but the select group of those skilled in the art.[17] Hindsight is a tempting way to ease that discomfort, especially because the introduction to these unfamiliar concepts is virtually always based on the disclosure of the invention itself. But what the fact finder can recreate only after using the patent as a guide cannot be the inquiry. *Dann*, 425 U.S. at 229, quoting *Graham*, 383 U.S. at 37. Similarly, the inquiry cannot be whether, in retrospect, the invention is "so simple" that it is not worthy of patent protection. *Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984) ("Judges are not constitut' ıally empowered to legislate their individual subjective views respecting degrees of inventiveness, a distinct approach

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[17] As discussed *supra*, the so-called secondary indicia (or secondary considerations) consider the real-world reaction taking the invention into account, but that it is not the same as considering what those of skill in the art thought absent knowledge of the invention under section 103(a).

from that of determining validity on the basis of the evidence and procedural rules.").

The TSM methodology performs a critical evidentiary function to prevent these dangers, ensuring the proper review of obviousness decisions by requiring evidence – some reason – supporting combination. That is why it considers the motivation of a person having ordinary skill in that art at that time (it is not about the inventor's own thought process). Absent this requirement, there is no means of weeding out decisions based on improper hindsight or subjective belief.[18] As explained *supra*, courts can draw upon a vast array of evidence – not just an explicit written suggestion – in support of an obviousness determination. While Petitioner and *amici* argue that the TSM analysis imposes an unduly high burden, in truth the burden is little more than a demand that the trial court or Patent Office articulate the basis for its decision.

B. TSM PROVIDES FLEXIBILITY

The legal standard for obviousness does not change case to case but the facts – the inventions and technology – do. Thus, the analytic framework must be adaptable. As Judge Learned Hand said in *Safety Car*, *supra*, there cannot be a single, objective test. The rule must be flexible to account for both changing facts and technology. *Graham*, 383 U.S. at 11-12, 17-19. This is what the Federal Circuit has done. *In re Eli Lilly & Co.*, 902 F.2d 943, 947 (Fed. Cir. 1990).

In the present case the technology is mechanical, which the *Ruiz* opinion correctly noted is "simpler" to analyze. *Ruiz*, 357 F.3d at 1276; *see McGinley v. Franklin Sports, Inc.*,

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[18] This worry applies to courts and juries, as in this case, and to the examination of patent applications. *See e.g., In re Kahn*, 441 F.3d at 986 (examiner's decision was based on improper hindsight when the examiner gave no basis to support conclusion that one of skill in the art would have combined references); *In re Rouffet*, 149 F.3d at 1358 (same).

262 F.3d 1339, 1351 (Fed. Cir. 2001) ("When the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting. Consequently, the tests of whether to combine references need to be applied rigorously.")(citations omitted). In more complex technologies, such as biotechnology, understanding the state of the art for an obviousness analysis is more difficult.

By looking through the eyes of one of ordinary skill in that art at the relevant time, TSM accounts for the different technologies. The long history of applying TSM demonstrates that it is well-adapted for the different circumstances in individual cases. As explained *supra*, the TSM analysis does not impose an inflexible rule of law demanding an explicit written suggestion in the prior art. To the contrary, it provides for multiple avenues of proof, allowing adaptation for different technologies and factual circumstances. *E.g., Dystar*, slip. op. at 8-9.

TSM's ability to account for wildly divergent fact patterns becomes clearer in reviewing how the methodology has been properly applied. For example, in *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 78 F.3d 540, the patent claimed a process for making partially-fried ("parfried") waffle-shaped french fries. The court found that the invention would have been obvious based on prior art disclosing waffle-shaped potato chips and the process for parfrying. *Id. at* 544-45. Applying the TSM analysis, the court found the motivation to combine from prior art disclosing the desirability of parfrying potato products and the suitability of the parfry process to waffle fries. *Id.* It stated that it was "the potato products resulting from these slicing devices, and not merely the devices themselves, that created the motivation to combine." *Id.* at 544.

Unpredictable technologies, like biotechnology, may require more explicit evidence supporting combination of known elements because of the state of knowledge in that

art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991), is such a case. It concerned genetic engineering techniques for producing specific proteins that are toxic to insects in cyanobacteria. The prior art taught producing these proteins in genetically engineered bacteria cells, and separate references taught that a different protein could be made in cyanobacteria. *Id.* at 492. The PTO Examiner and appeal board found the invention obvious, holding that one of ordinary skill in the art would have been motivated to use cyanobacteria because they were attractive hosts for the expression of proteins. *Id.* at 492, 494. The Federal Circuit reversed, finding that obviousness could not be sustained on that record because there was no suggestion, either explicitly or implicitly, in the prior art that one of ordinary skill would reasonably expect the substitution to be successful. *Id.* at 495.[19]

While the legal standard for a TSM analysis remains unflinching, it is a flexible standard that may be applied case-specifically based upon the technology, art and circumstances. A *per se* rule of law that ignores these factors cannot adequately accommodate the diverse facts present in any given case because obviousness is an inquiry based on complex underlying facts. *Graham*, 383 U.S. at 17-18; *Eli Lilly*, 902 F.2d at 947.

The danger of *per se* rules becomes apparent when asking why the prior art might be silent on whether to combine elements. It could be because (1) the subject matter was so obvious that it would not be addressed in the written prior art, or (2) the idea is inventive and one that has not previously occurred to those of ordinary skill in the art. If,

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[19] TSM does not preclude obviousness simply because the art is unpredictable. *See e.g., In re O'Farell*, 853 F.2d 894, 902 (Fed. Cir. 1988)(finding method of producing a protein in a bacterial host obvious in view of prior art containing a "detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful").

as Petitioner suggests, an invention should be presumed obvious when the elements are old – unless the inventor can show the opposite, such as a complete rejection of the premise underlying the inventor's work (a so-called "teaching away"[20]) – the standard would account only for the former, and would improperly deny patents to the latter. This is the very reason why *Graham* recognized that the concept of "invention" is amorphous and called for a "functional approach to questions of patentability." *Graham*, 383 U.S. at 11-12. The TSM framework meets this demand and is well-suited to adapt between scenarios and thus more likely to provide correct determinations.

C. PRECEDENT PROVIDES CERTAINTY

This Court has more than once advised "that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002), *citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). The patent system is vital to the American economic and legal system. *See* http://www.federalreserve.gov/BoardDocs/speeches/2003/20030404/default.htm (Statement by then-Federal Reserve Commissioner Alan Greenspan). In other words, the certainty of this well-defined system should not be upset unduly.

The *Festo* Court correctly described *Warner-Jenkins* as a situation where "[t]he petitioner ... requested another bright-line rule that would have provided more certainty in determining when estoppel applies but at the cost of disrupting the expectations of countless existing patent

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[20] Teaching away is one of the recognized secondary considerations. *See In re Mercier*, 515 F.2d 1161, 1166 (CCPA 1975)("The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention."), *citing In re Lunsford*, 357 F.2d 380 (CCPA 1966).

holders." *Festo*, 535 U.S. at 739. This Court rejected that artificial assertion of "certainty" concerning infringement, acknowledging that the flexibility of the doctrine of equivalents and prior rules of patent prosecution were more important. *Id.* So too for obviousness.

There is a significant history and background to the TSM analysis that should not be overturned in favor of new standards, as proposed by some. The current approach is both robust and flexible, and amending it would only create new problems and potentially transform the patent system into a "cruel hoax."[21] Over the course of almost half a century, the courts have refined and articulated a standard for obviousness that is functional and understood by applicants and inventors, by the PTO and courts, as well as by litigants.[22] In short, the Federal Circuit has done exactly

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[21] In 1979, Donald W. Banner, then Commissioner of Patents and Trademarks, wrote:

> [People] will be interested in the patent system only so long as they can reasonably understand the patent laws and rely on their stability. ... [Otherwise,] inventors and businessmen will turn their backs on the patent system. Indeed, when the government grant of a patent cannot reasonably be relied upon throughout the nation, then the patent system becomes a cruel hoax.

Foreword, ULTIMATE CONDITION, at p. v.

[22] A recent article surveying Federal Circuit obviousness decisions found that the court affirms determinations of obviousness in a clear majority of cases (75.3% for bench trials; 81.1% where JMOL was denied, and 64.1% from the PTO). Lee Petherbridge & R. Polk Wagner, "The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness", p. 36, *available at* http://lsr.nellco.org/upenn/wps/papers/103. The Federal Circuit affirmed only 39.7% of obviousness summary judgment decisions. *Id.* The study countered commonly held beliefs that the bar to patentability has been lowered by the Federal Circuit and showed that patent claims were found unpatentable for obviousness in a majority of cases, overall about 58%. *Id.* at p. 5. This rate has remained generally consistent from 1990 to 2005, and the reversal rate of PTO decisions has decreased. *Id.* at p. 34, Fig. 1 and p. 40, Fig. 3. Thus, TSM does create certainty; to change it would upset the settled expectations unduly.

what it was created to do – provide a measure of certainty in the application of patent standards. *See, e.g.*, S. Rep. No. 97-275 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 14-15.

The current debate, involving vastly different readings of this Court's decision in *Graham*, shows neither *Graham* nor any other single case can provide the certainty of a doctrine applied over many years and in many different factual situations. Petitioner's attempt to wipe the slate clean and start anew cannot provide certainty. This approach would inevitably result in confusing the proper standard to be applied to any particular invention and in any technology. Even the Petitioner acknowledges that this type of dramatic change is ill-advised. Petitioner's Brief at 44 ("Any judicial change from these long-accepted and applied rules should proceed incrementally, in the common-law method, not by sudden disregard for an entire corpus of case law.") TSM should not be jettisoned.

D. PETITIONER'S AND AMICI'S PROPOSALS ARE INAPPROPRIATE

Petitioner and some *amici* use this case as a vehicle for attacking the patent system as a whole and challenging the rules of patent prosecution (despite the fact that Congress has amended some prosecution rules, such as those for patent expiration, since the patent-in-suit issued).[23] Those rules and regulations are not present in this case and they are not material to the analysis of section 103(a) or its application by lower courts. Most of the real complaints voiced by Petitioner and *amici* concern funding for the Patent and Trademark Office and its operations, which are more appropriately addressed in administrative and

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[23] *See, e.g.*, Petitioner's Brief at 42; BSA Brief at 2; *Cf. Graham*, 383 U.S. at 18-19.

Congressional venues. [24] The U.S. Federal Trade Commission and National Academy of Sciences Reports cited to this Court also highlight the funding issues. [25] Nonetheless, a number of "new" proposals have been set forth and AIPLA will address some of them briefly.

One "historical" test referred to by Petitioner and *amici* is the so-called synergy test, allegedly set forth in *Anderson's Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), and *Sakraida v. Ag Pro, Inc.* 424 U.S. 273 (1976). Neither decision, however, purports to overrule the principles established in *Graham* (which does not mention a "synergy" test) or to set forth a higher standard for "combination" patents requiring evidence of a synergistic result as a prerequisite to non-obviousness. *See Graham*, 383 U.S. at 12 ("The *Hotchkiss* formulation, however, lies not in any label, but in its functional approach to questions of patentability."). The Tenth Circuit explicitly rejected the premise that either case created a synergy test. *Plastic Container Corp. v. Continental Plastics, Inc.*, 607 F.2d 885, 904-05 (10th Cir. 1979).

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[24] *See, e.g.*, Statement of James E. Rogan [then Commissioner of the Patent and Trademark Office] Before the Subcommittee on Courts, the Internet and Intellectual Property, Apr. 3, 2003, on the United States Patent and Trademark Fee Modernization Act Of 2003, *available at* http://www.uspto.gov/web/offices/com/speeches/stratplan2003apr03rogan.htm); General Accounting Office, Intellectual Property Report at 3, Aug. 2002, *available at* http://www.gao.gov/new.items/d02907.pdf#search=%22General%20accounting%20office%20report%20%22august%202002%22%20%22Intellec-tual%20Property%22.

[25] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf, at pp. 18-19, Chapter 6 (Competition and Patent Policy)("[M]any participants noted that the [US]PTO lacks the funding necessary consistently to make high-quality determinations as to whether patent applications deserve to be granted.); National Academy of Sciences, "A Patent System for the 21st Century" (April 19, 2004), *available at* http://www.nap.edu/books/0309089107/html, at pp. 107-108.

In *Anderson's*, the invention involved connecting mechanical parts previously known to perform a given function into a single machine. 396 U.S. at 58. Each individual part in the claimed invention was not dependent on the operation of another and each performed its expected function with no real interaction. *Id.* at 59-60. The same is true in *Sakraida*, where the Court observed that "this patent simply arranges old elements with each performing the same function it had been known to perform." 425 U.S. at 282. Neither decision differs from a TSM analysis, which is equally suited to find a combination obvious where there is a reason to find that the prior art taught or suggested the combination, regardless of its effects on functionality. The synergy test, on the other hand, cannot achieve a proper balance since it bypasses the issue of whether one of ordinary skill would have combined prior art and only asks whether in hindsight the results would have been explainable.

It is unclear whether Petitioners and *amici* believe the "synergy" test would be applicable to all patents or only a subclass of "combination patents." Nothing in any precedent by this Court, however, has carved out a special category of patents as "combination patents." Perhaps such a special category is implicit in the understanding of one of ordinary skill in the art where these elements already exist – but that it is not a legal test.

As discussed *supra*, the concept of "combination" is a misnomer since all inventions draw upon what came before them. The false premise of labeling certain inventions as "combination patents" separate from all other inventions is unwarranted.

> The reference to a "combination patent" is equally without support in the statute. There is no warrant for judicial classification of patents, whether into "combination" patents and some other unnamed and undefined class or other-

> wise. Nor is there warrant for differing treatment or consideration of patents based on a judicially devised label. Reference to "combination" patents is, moreover, meaningless. Virtually all patents are "combination patents," if by that label one intends to describe patents having claims to inventions formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a "non-combination" invention, i.e., an invention consisting of a single element.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540 (Fed. Cir. 1983). Those proposing change fail to specify how obviousness would be considered for non-combination patents. While inventions in the mechanical arts can be visualized as combinations, it is difficult to apply the same label to a compound or a chemical that cannot be broken down into separate parts (although elements of a chemical the structure – such as particular moieties – can be found in the prior art as separate parts too).

Some briefs, like the Government's, have proposed tests that ignore the burdens established in section 103(a) itself and require that an inventor prove nonobviousness, *i.e.* prove a negative. This is contrary to the Patent Code. For instance, Section 102 (note 10, *supra*) provides that an applicant is "entitled to a patent unless," clearly placing the burden on the PTO to show that an invention is unpatentable.[26] Similarly, in litigation involving an issued

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[26] The Government's brief, at p. 26, claims that the Federal Circuit has "devalued the PTO's central role in determining whether a claimed invention is patentable." *Dickinson v. Zurko*, 527 U.S. 150 (2000), establishes that PTO fact-finding is due the same deference accorded other federal agencies, the "substantial evidence" standard (5 U.S.C. § 706(2)(E)). *See In re Gartside, supra.*

patent, 35 U.S.C. § 282 provides that "[a] patent shall be presumed valid," including when section 103(a) is a defense.

The mischief that can be caused by the proposals raised by Petitioner and *amici* can be seen by looking at the Government's brief. It makes the amazing assertion, *e.g.*, at page 10, that patents should only issue for extraordinary inventions. It is just this sort of overreaching that shows how the system can go astray without an established standard. The standard already exists and it should be affirmed.

CONCLUSION

On the facts as presented, the Court should hold in favor of Respondents and affirm the remand for further proceedings. Such a ruling would not be a final determination of whether the invention would have been obvious, but would only require that it be determined in the proper analytic framework.

Section 103(a)'s language itself articulates two critical points: (1) the inquiry must focus on "the subject matter as a whole," not the individual elements of the invention; and (2) the inquiry must focus on whether the invention as a whole was obvious to one of ordinary skill in the relevant art, not whether that person would be capable of assembling individual elements absent some reason to do so.

Thus, the statute recognizes that it is not enough to identify individual elements of an invention in the prior art whether or not they could theoretically be assembled by one of ordinary skill in the art using existing tools. Obviousness demands more. Without a suggestion to combine, the danger that section 103(a) obviousness could become little more than the application of section 102 anticipation on a part-by-part basis was immediately recognized by the courts. Over the course of more than 40 years of decisions, the CCPA, and later the Federal Circuit, have developed an analytic framework for just this protection. It is an appropriate standard that should be confirmed.

Respectfully submitted,

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